# 4 KIDS COLD N COUGH GRAPE FLAVOR- onion, calcium sulfide, goldenseal, sodium chloride, phosphorus, anemone pulsatilla, and sulfur liquid Hyland's

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

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# 4 Kids Daytime Cold & Cough Grape Flavor

Relieves congestion, runny nose, sore throat, sneezing, cough and post nasal drip

### **Drug Facts**

# Active ingredients

Allium Cepa 6X HPUS watery/runny nose,cold, hacking cough, painful throat
Hepar Sulph Calc 12X HPUScold, sneezing
Hydrastis 6X HPUSrattling/tickling cough, sinus congestion, dry/raw/sore throat
Natrum Muriaticum 6X HPUS dry cough, sore throat
Phosphorus 12X HPUShoarse/dry cough, nasal congestion, chest congestion
Pulsatilla 6X HPUSmoist cough, cold, post nasal drip
Sulphur 12X HPUSchest congestion, nasal congestion, sneezing, runny nose

"HPUS" indicates that the active ingredients are in the official Homeopathic Pharmacopœia of the United States.

#### Uses

■ Temporarily relieves symptoms of common cold in children, including:
□ runny nose □ sore throat □ sneezing
□ cough □ post nasal drip
□ nasal or chest congestion

# Warnings

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Ask a doctor before use if you have:** ■ persistent or chronic cough such as

smoking, asthma, chronic bronchitis or emphysema. A persistent cough may be a sign of a serious condition. 

cough that is accompanied by excessive phlegm (mucus).

**Stop use and ask a doctor if:** ■ symptoms persist for more than 7 days or worsen. ■ inflammation, fever or infection is present or develops. ■ cough tends to recur or is accompanied by a fever, rash or persistent headache.

As with any drug, ask a doctor before use if pregnant or breast-feeding. Keep this and all medications out of the reach of children.

#### **Directions**

■ Use as directed. ■ Do not refrigerate. ■ Shake well before using. ■ Measure only with the dosing cup provided. ■ Do not use dosing cup with other products. ■ On dosing cup, mL = milliliter.

Children 2 years	5 mL up to 6 times per day
to under 6 years	(every 4 hours).
Children 6 years	10 mL up to 6 times per day
to under 12 years	(every 4 hours).
Adults and children	15 mL up to 6 times per day
12 years and over	(every 4 hours).

# Inactive ingredients

Citric Acid, Glycerine, Glycyrrhiza Extract, Natural Grape Flavoring, Purified Water, Sodium Benzoate.

#### **Questions or comments?**

(800) 624-9659

\*CLAIMS BASED ON TRADITIONAL
HOMEOPATHIC PRACTICE, NOT ACCEPTED
MEDICAL EVIDENCE. NOT FDA EVALUATED.
DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING.

#### PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

Hyland's

**NATURALS™** 

• Kids •

Cold &

Cough

DAYTIME

NO ALCOHOL, SUGAR,

PARABENS or DYES

Congestion

Runny Nose

Sore Throat

Cough

Post Nasal

Drip

2-12

YEARS

NATURAL

**GRAPE FLAVOR** 

4 FL. OZ. (118 mL)

**HOMEOPATHIC** 



# **4 KIDS COLD N COUGH GRAPE FLAVOR**

onion, calcium sulfide, goldenseal, sodium chloride, phosphorus, anemone pulsatilla, and sulfur liquid

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3243
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL		
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL		
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL		
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6 [hp_X] in 1 mL		

PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: 176KB35JEV) (ANEMONE PULSATILLA - UNII:176KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	GRAPE (Natural Grape Flavor)	Imprint Code
Contains		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:54973- 3243-1	1 in 1 CARTON	02/10/2016			
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:54973- 3243-2	1 in 1 CARTON	02/10/2016			
2		236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
3	NDC:54973- 3243-3	5 mL in 1 POUCH; Type 0: Not a Combination Product	02/10/2016			
4	NDC:54973- 3243-4	1 in 1 CARTON	02/10/2016			
4		148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	02/10/2016		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

# **Registrant -** Standard Homeopathic Company (Hyland's) (008316655)

Establishment				
Name	Address	ID/FEI	Business Operations	
Standard Homeopathic Company		008316655	manufacture(54973-3243), pack(54973-3243)	

Establishment			
Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		080253323	manufacture(54973-3243) , pack(54973-3243) , label(54973-3243)

Establishment			
Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		876754375	manufacture(54973-3243) , pack(54973-3243)

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